

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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1915-9-8

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HM22/0717

EXAMINER

CHARLES AEE, F

ART UNIT

PAPER NUMBER

1656

DATE MAILED:

07/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/729,332

Applicant(s)

ARIMORI ET AL.

Examiner

Fariba Ghashghaee

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 22-51, 57 and 58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-21, 52-56, 59 and 60 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 22-51, 57 and 58 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6. 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-21, 52-56, 59 and 60 are drawn to a modular fluorescence sensor for detection of saccharides, classified in class 436, subclass 501.
- II. Claims 22-39, drawn to a method for synthesizing a modular fluorescence sensor, classified in class 436, subclass 172.
- III. Claims 40-51, 57 and 58 are drawn to a method for detecting an analyte contained in a sample, classified in class 436, subclass 500.

The inventions are distinct, each from the other because:

Inventions of group I and II are related as process of making and product made.

The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the modular fluorescence sensor for the detection of glucose could be made by any simple chemical synthesis procedure.

Inventions of group I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the detection of

blood sugar or blood sugar could be done by any drugs and kits available in the market for the detection of glucose.

Inventions of group II and III are related as process of making and process of using the product. The use as claimed can not be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(i)).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with WEI-NING YANG on June 29, 2001 a provisional election was made without traverse to prosecute the invention of group I, claims 1-21, 52-56, 59 and 60. Affirmation of this election must be made by applicant in replying to this Office action. Claims 22-51, 57 and 58 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-21, 52-56, 59 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sandanayake et al. ("Two Dimensional Photoinduced Electron Transfer (PET) Fluorescence Sensor for Saccharides", Chem. Lett. 1995, 503-504), and further in view of Antwerp et al. (US Pat. 6,002,954).

Sandanayake et al. teaches a fluorescence sensor for saccharides comprising phenyl boronic acids attached to an amine group in ortho position and a straight-chain aliphatic spacer with six carbon atoms (See page 503, formula 2). Sandanayake also teaches the binding and the stability constants for the binding of the fluorescence sensor to saccharides and to glucose (See table 1).

Sandanayake does not teach the attachment of the sensor to the solid support.

Antwerp discloses a fluorescence sensor comprising phenyl boronic acid and amine group and an anchor group to attach the fluorescence sensor to the solid support (See column 8, formula I, and column 10, line 22-column 11, line 33).

It would be obvious to provide stable attachment of the sensor to a micrometer scale particle because the size of the particle is a measurement parameter which could be achieved by experimentation. Furthermore, Since Antwerp discloses that these sensors could be attached to any fluorescent dye or a luminescent dye or a colorimetric dye (See column 8, lines 41-47), therefore these sensors could be used in flow cytometry.

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the method of Sandanayake with method of Antwerp to make the claimed fluorescence sensors because Antwerp et al. states that " In order to use the amplification components for analyte sensing in vivo, the components for the reactions must be immobilized in a polymer matrix that can be implanted subdermally". An ordinary practitioner would have been motivated to attach an anchor to the amine group of the sensor to immobilize it on the solid support.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fariba Ghashghaee whose telephone number is

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Art Unit: 1656

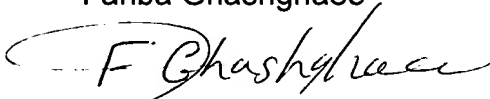
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(703)305-3586. The examiner can normally be reached on 8:30 A.M.-4:30 P.M. on Mon.-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703)308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3014 for regular communications and (703)305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

Fariba Ghashghaee



July 15, 2001



JEFFREY FREDMAN
PRIMARY EXAMINER